

USE OF CARBOHYDRATE SOURCE TO LIMIT WEIGHT GAIN IN CATS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of the following U.S. patent applications, the disclosures of which are incorporated herein by reference: Serial No. 09/268,919, filed March 16, 1999; Serial No. 09/507,066, filed February 18, 2000 and claiming priority to U.S. provisional application Serial No. 60/121,087, filed February 23, 1999; and Serial No. 09/609,622, filed July 5, 2000 and claiming priority to U.S. provisional application Serial No. 60/143,032, filed July 9, 1999.

BACKGROUND OF THE INVENTION

This invention relates to a process of administering a pet food composition to prevent obesity in companion animals, such as cats and dogs. More particularly, the invention relates to a process for limiting weight gain in cats. The invention is further directed to a process for decreasing the postprandial blood glucose and insulin response in cats to promote satiety and a voluntary decrease in food intake.

Obesity is a significant health concern in companion animals. Veterinary care professionals have reported that approximately 20 – 40% of the pets in their care are overweight. These animals bear a greater risk for health problems associated with the respiratory, cardiovascular, and skeletal systems. More particularly, obese feline patients have demonstrated greater susceptibility to diseases such as diabetes mellitus, osteoarthritis, ligament injuries, perineal dermatitis, cardiomyopathy, and hepatic lipidosis. Accordingly, new technologies meeting the health needs of obese feline patients are in high demand by pet owners and veterinarians alike.

The causes of feline obesity include sedentary lifestyle and confinement indoors, as well as improper nutrition, genetic predisposition, and hormonal disorders such as thyroid and pituitary gland dysfunction. Moreover, spayed and neutered cats often exhibit a decrease in their physical activity and metabolism and therefore, have a greater tendency to gain weight.

An effective weight loss regimen for cats includes a two-tiered approach involving increasing the amount of exercise the animal undergoes, while also decreasing the amount of calories ingested by the animal. It has been suggested that pet owners can increase their cat's daily exercise through harnessed walks, or several periods of play with a favorite toy. However, the challenge in combating feline obesity is providing a diet that fulfills the feline patient's nutritional requirements, while still lowering the animal's caloric intake and promoting satiety.

In an attempt to meet this challenge, pet owners are often faced with a choice between limiting their pet's food intake by restricting the amount of food made available to the pet, or providing the pet with a dietary formulation that contains less of those ingredients that have been shown to promote obesity. Given these choices, some prefer to accept the fact that their pets will either become or remain overweight. Unfortunately, as is the case with humans, excess body fat can have serious health implications.

Current nutritional recommendations for treatment of obesity in companion animals include the consumption of diets high in fiber to dilute the caloric content thereof. However, high fiber diets are often associated with several undesirable side effects that include decreased palatability of food, improper mineral balance, decreased food digestibility, increased stool volume, constipation and/or increased frequency of defecation, and poor skin and hair coat. Unfortunately, although high fiber diets have been available for many years, the prevalence of obesity in companion animals has continued to increase.

In addition, impaired glucose metabolism and hyperinsulinemia, together with abnormal blood glucose and insulin responses, have been associated with obesity in companion animals, including overweight cats. In general, when high blood glucose levels are maintained, the body can use the extra glucose to produce fats. Storage of these fats contributes to weight gain. By enhancing fat synthesis, this metabolic alteration can lead to continued weight gain and further the progression of obesity.

U.S. Patent No. 5,932,258 and U.S. patent application Serial Nos. 09/268,919 and 09/507,066, which are incorporated herein by reference, describe feeding diets to companion animals that contain a carbohydrate source other than rice as effective for

controlling the postprandial glycemic and insulin response. These references teach that by counteracting the effects of impaired glucose metabolism and hyperinsulinemia, such a diet can help lessen the progression of obesity. However, the preceding references do not teach a diet containing a carbohydrate source that assists in weight management in cats.

U.S. Serial No. 09/609,622, which has been incorporated herein by reference, teaches a process for promoting weight loss in a mammal by feeding a composition that contains a source of carbohydrates selected from a low glycemic index grain, such as sorghum, barley, corn, and blends thereof. This reference further teaches that reducing starch levels and/or selecting sources of carbohydrates having low glycemic indices improves glucose metabolism, resulting in fewer abrupt rises and drops in blood glucose levels. As a result, the individual feels satiated more often, consumes less food, and loses weight.

It would be desirable to be able to improve body composition in obese feline animals by decreasing their caloric intake. It would also be desirable to be able to maintain favorable body composition, in even seemingly healthy cats with no overt symptoms, to prevent the onset of obesity in those animals that have a tendency to become obese. Accordingly, there is a need in the present art to develop alternative nutritional means to prevent obesity in cats.

SUMMARY OF THE INVENTION

The present invention meets that need by providing a process of administering a pet food composition to limit weight gain in a cat. In accordance with one aspect of the present invention, a process is provided for limiting weight gain in a cat comprising the step of feeding the cat a pet food composition comprising a source of protein, a source of fat, and a source of carbohydrates from a grain source that excludes rice. It has been found that a pet food composition that employs as the carbohydrate source a low glycemic index grain, which is selected from the group consisting of corn, sorghum, barley, oats, and blends thereof, when fed to a cat, has the effect of decreasing the postprandial blood glucose and insulin response of the cat as compared to diets using

rice as the primary carbohydrate source. Preferably, the grain source has a glycemic index that is less than rice.

Reducing starch levels and/or selecting sources of carbohydrates/starches having low glycemic indices improves glucose metabolism in cats. Improved glucose metabolism results in fewer abrupt rises and drops in blood glucose levels. Accordingly, feeding the pet food composition of the present invention ad libitum, promotes satiety in the cat. This effect promotes a voluntary decrease in food intake resulting in less weight gain than if the cat had been fed a diet that employs or includes rice or other high glycemic index starch as the carbohydrate source. This effect is even more pronounced when the composition is fed to male cats.

Where the low glycemic index grain source is a blend of corn and sorghum, it is preferred that these starch sources be present in the composition in a weight ratio from between about 1:5 to about 5:1, more preferably from about 1:3 to about 3:1, and most preferably about 1:1. Where the low glycemic index grain source is a blend of corn, sorghum, and barley, or corn, sorghum, and oats, it is preferred that these starch sources be present in the composition in a weight ratio of from between about 1:1:5 to about 1:5:1 to about 5:1:1, more preferably from about 1:1:3 to about 1:3:1 to about 3:1:1, and most preferably from about 1:1:1, respectively.

The composition can comprise from about 25 to about 45% crude protein, from about 4 to about 30% fat, from about 2 to about 20% total dietary fiber, and a source of carbohydrates that excludes rice, but includes a low glycemic index grain source such as corn, sorghum, barley, oats, and blends thereof. Typically, the carbohydrate sources in the composition of the present invention will make up from about 35 to about 60 weight percent of the composition.

The pet food composition may further comprise from about 1 to about 11 weight percent of supplemental total dietary fiber of fermentable fibers that have an organic matter disappearance of 15 to 60 weight percent when fermented by fecal bacteria for a 24 hour period.

Accordingly, it is a feature of the present invention to provide a composition and process of administering it to limit weight gain in cats. This, and other features and

advantages of the present invention, will become apparent from the following detailed description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a graph of the influence of a sorghum-based diet of the present invention as compared to a rice-based diet on food intake (kcal/day). The value for the rice-based diet reflects the mean intake increase $[(42.02 \times 3) + (19.62 \times 5)]$ multiplied by the caloric density (461.949 kcal/100g). The value for the sorghum-based diet reflects the mean intake increase $[(18.86 \times 3) + (13.94 \times 5)]$ multiplied by the caloric density (469.316 kcal/100g).

Fig. 2 is a graph of the influence of a sorghum-based diet of the present invention as compared to a rice-based diet on weight gain (g).

Fig. 3 is a plot diagram of the influence a 15-minute exposure to a rice-based diet has on plasma glucose concentration. Mean plasma glucose concentration is expressed in (mg/dl).

Fig. 4 is a plot diagram of the influence a 15-minute exposure to a rice-based diet has on plasma insulin concentration. Mean plasma insulin concentration is expressed in (μ U/ml).

Fig. 5 is a plot diagram of the influence a 15-minute exposure to a sorghum-based diet of the present invention has on plasma glucose concentration. Mean plasma glucose concentration is expressed in (mg/dl).

Fig. 6 is a plot diagram of the influence a 15-minute exposure to a sorghum-based diet of the present invention has on plasma insulin concentration. Mean plasma insulin concentration is expressed in (μ U/ml).

Fig. 7 is a graph of average plasma glucose concentrations in two groups of 8 cats fed either a rice-based diet or a sorghum-based diet of the present invention. Average plasma glucose concentrations are expressed in (mg/dl).

Fig. 8. is a graph of average plasma insulin concentrations in two groups of 8 cats fed either a rice-based diet or a sorghum-based diet of the present invention. Average plasma insulin concentrations are expressed in (μ U/ml).

Fig. 9. is a graph of incremental peak glucose values in cats fed either a rice-based diet or a sorghum-based diet of the present invention. Glucose concentration is expressed in (mg/dl).

Fig. 10. is a graph of incremental peak insulin values in cats fed either a rice-based diet or a sorghum-based diet of the present invention. Insulin concentration is expressed in (μ U/ml).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention utilizes a pet food composition that excludes rice but includes a low glycemic index grain source that aids in limiting weight gain in cats. Preferably, the grain source has a glycemic index that is less than rice.

Reference is made to co-pending U.S. patent application Serial No. 09/609,622, which has been incorporated herein by reference for its teaching of low glycemic index grains. Glycemic index is a measure of the rate at which carbohydrates are broken down into glucose and absorbed by the bloodstream. Glycemic index is a relative scale measured from a reference standard food (normally 50 gm white bread = 100). By "low glycemic index" it is meant that the starch source provides a glycemic response that is closer to fasting glucose and insulin levels than a reference standard carbohydrate source.

Suitable low glycemic index grains for use with the present invention include corn, sorghum, barley, oats, and blends thereof. Preferred blends of low glycemic index grains can include corn and sorghum; corn, sorghum, and barley; or corn, sorghum, and oats. Brewer's rice is not a suitable grain source for the present invention. In a healthy feline animal, the presence of rice as a dietary starch source affects the animal in that it eats more and gains more weight. Feeding the pet food composition of the present invention ad libitum, which comprises sources of carbohydrates having low glycemic indices, affects the animal in that it feels satiated more often, resulting in a voluntary decrease in food intake and less weight gain. This effect is even more marked in male felines.

The pet food composition can be any suitable pet food formula that also provides adequate nutrition for the cat. For example, a typical feline diet for use in the present

invention may contain from about 25 to about 45% crude protein (and preferably from about 25 to about 35%), from about 4 to about 30% fat (and preferably from about 10 to about 18%), and from about 2 to about 20% total dietary fiber, along with the starch source, all percentages by weight. Typically, the carbohydrate sources in the composition of the present invention will make up from about 35 to about 60 weight percent, and preferably from about 40 to about 55 weight percent, of the composition. A preferred source of corn is ground corn meal.

The pet food composition of the present invention may also optionally contain a source of fermentable fibers that display certain organic matter disappearance percentages. The fermentable fibers that may be used have an organic matter disappearance (OMD) of from about 15 to 60 percent when fermented by fecal bacteria in vitro for a 24 hour period. That is, from about 15 to 60 percent of the total organic matter originally present is fermented and converted by the fecal bacteria. The organic matter disappearance of the fibers is preferably 20 to 50 percent, and most preferably is 30 to 40 percent.

Thus, in vitro OMD percentage may be calculated as follows:

$$\{1 - [(OM \text{ residue} - OM \text{ blank}) / OM \text{ initial}]\} \times 100,$$

where OM residue is the organic matter recovered after 24 hours of fermentation, OM blank is the organic matter recovered in corresponding blank tubes (i.e., tubes containing medium and diluted feces, but no substrate), and OM initial is that organic matter placed into the tube prior to fermentation. Additional details of the procedure are found in Sunvold et al., J. Anim. Sci. 1995, vol. 73:1099-1109.

The fermentable fibers may be any fiber source that intestinal bacteria present in the animal can ferment to produce significant quantities of short chain fatty acids (SCFAs). "Significant quantities" of SCFAs, for purposes of this invention, are amounts over 0.5 mmol of total SCFAs/gram of substrate in a 24-hour period. Preferred fibers include beet pulp, gum arabic (including gum talha), psyllium, rice bran, carob bean gum, citrus pulp, pectin, fructooligosaccharides and inulin, mannanoligosaccharides and mixtures of these fibers.

The fermentable fibers are used in the pet food composition in amounts from 1 to 11 weight percent of supplemental total dietary fiber, preferably from 2 to 9 weight

percent, more preferably from 3 to 7 weight percent, and most preferably from 4 to 7 weight percent.

A definition of "supplemental total dietary fiber" first requires an explanation of "total dietary fiber". "Total dietary fiber" is defined as the residue of plant food that is resistant to hydrolysis by animal digestive enzymes. The main components of total dietary fiber are cellulose, hemicellulose, pectin, lignin, and gums (as opposed to "crude fiber", which only contains some forms of cellulose and lignin). "Supplemental total dietary fiber" is that dietary fiber which is added to a food product above and beyond any dietary fiber naturally present in other components of the food product. Also, a "fiber source" is considered such when it consists predominantly of fiber.

Typically, the amount of the pet food composition of the present invention that can be provided to a cat can be between about 40 and about 110 g/day when fed ad libitum.

In order that the invention may be more readily understood, reference is made to the following example that is intended to illustrate the invention, but not limit the scope thereof.

Example 1

Two groups of eight young adult neutered and ovariectomized cats (6 males and 10 females) were used. The ages of the cats ranged from approximately 1 to 5 years of age and were of normal body weight at the initiation of the study. The procedures for this study and the care and handling of these animals were reviewed and approved by the Animal Experimentation Ethics Committee and the cats were treated humanely and ethically during the entire study period.

The cats were housed individually for a minimum of two weeks to become accustomed to the test holding facilities. The cats were then transferred to a different facility where they were group housed for approximately 3-4 months. Prior to the initiation of the study the animals were fed a dietary composition, which consisted of a commercially available dry cat food (Iams Original Formula Cat Food).

During the study period, two experimental dietary compositions were provided to the animals. Both experimental diets were chicken-based and formulated to provide for

the maintenance needs of adult cats. The diets were essentially identical in nutrient composition and caloric content, but varied in the starch (primary carbohydrate) source. One experimental diet was rice-based, while the other had a blend of corn and grain sorghum. The ingredient composition of the two experimental diets is summarized in

5 Table 1 below.

Table 1. Ingredient Composition of Experimental Diets Tested

INGREDIENT	RICE-BASED DIET (% OF MIX)	CORN/SORGHUM- BASED DIET (% OF MIX)
Brewers Rice	40.7	
Corn		24.1
Sorghum		24.1
Chicken By Product Meal	23.5	23.5
Chicken	14.8	6.9
Chicken Fat	6.1	5.7
Beet Pulp	5.0	5.0
Egg	3.2	3.2
Chicken Digest	2.6	2.6
Fish Meal	1.0	1.0
Brewers Yeast	0.5	0.5
Sodium Chloride	0.5	0.6
Potassium Chloride	0.5	0.4
DL-Methionine	0.3	0.4
Minerals	0.3	0.3
Vitamins	0.3	0.3
Choline Chloride	0.3	0.3
Dicalcium Phosphate	0.2	0.6
Calcium Carbonate	0.2	0.6

10 The nutrient composition of the two experimental diets is summarized in Table 2 below.

Table 2. Nutrient Composition of Experimental Diets Tested

NUTRIENTS	RICE-BASED DIET	CORN/SORGHUM- BASED DIET
Protein	37.21%	32.62%
Moisture	00.00%	00.00%
Ash	07.56%	07.29%
Fat	15.82%	15.59%
Crude Fiber	02.25%	02.53%
Metabolizable Energy	5039.83 kcal/kg	5090.19 kcal/kg
Carbohydrate	35.45%	36.71%
Calcium	01.30%	01.30%
Phosphorus	01.20%	01.10%

At the initiation of the study, the body weight (lbs.) of each cat was measured and recorded. The animals then began a 6-week period of maintenance feeding, during which the cats were fed a daily amount of food to maintain body weight. After concluding the 6-week period of maintenance feeding, body weights were again measured and recorded. The cats were then fed ad libitum for an additional 8-week period, after which body weights were again measured and recorded. The initial body weights, as well as the body weights recorded and changes in body weight after the 6-week period of maintenance feeding and the 8-week period of ad libitum feeding are presented in Table 3 below.

Table 3. Weight Changes

RICE-BASED DIET	INITIAL WEIGHT	WEIGHT AFTER 6 WEEKS	WT. AFTER 8 WEEKS AD LIB.	CHANGE IN WT. AFTER 6 WKS. MAINT.	CHANGE IN WT. AFTER 8 WKS. AD LIB.
Leroy	8.40	8.50	10.00	0.10	1.50
Cooper	7.60	7.75	9.00	0.15	1.25
Dash	6.85	6.90	7.45	0.05	0.55
Minstral	6.25	6.40	7.00	0.15	0.60
Lucifer	6.30	6.15	6.45	-0.15	0.30
Scarlet	5.35	5.35	5.45	0.00	0.10
Jasmine	5.10	5.15	5.55	0.05	0.35
Nutmeg	4.50	4.40	4.40	-0.10	0.00
Mean	6.29	6.33	6.91	0.031	0.581
SD	1.309	1.371	1.884	0.110	0.534
CORN/SORGHUM-BASED DIET	INITIAL WEIGHT	WEIGHT AFTER 6 WEEKS	WT. AFTER 8 WEEKS AD LIB.	CHANGE IN WT. AFTER 6 WKS. MAINT.	CHANGE IN WT. AFTER 8 WKS. AD LIB.
Abe	8.60	8.80	9.40	0.20	0.60
Lionall	7.10	7.20	7.40	0.10	0.20
Sophie	6.90	7.10	8.05	0.20	0.95
Tabatha	6.15	6.30	7.30	0.15	1.00
Rudolf	5.55	5.40	6.00	-0.15	0.60
Eclaire	6.00	5.95	6.40	-0.05	0.45
Meg	4.40	4.40	4.40	0.00	0.00
Romany	5.25	5.20	5.15	-0.05	-0.05
Mean	6.24	6.29	6.76	0.050	0.469
SD	1.290	1.386	1.613	0.131	0.398

Food intake (g) was measured daily and calculated as the amount of food eaten in 15 minutes on the actual test day (MRT). MRT food intake is presented in Table 4 below as a value of both grams/day and kcal/day.

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Table 4. MRT Food Intake

RICE-BASED DIET	TEST 1 IAMS g/day	TEST 2 RICE g/day	TEST 3 RICE g/day	TEST 1 IAMS kcal/day	TEST 2 RICE kcal/day	TEST 3 RICE kcal/day
Leroy	35	25	20	156.9	115.5	92.4
Cooper	40	30	55	179.3	138.6	254.1
Dash	40	25	30	179.3	115.5	138.6
Minstral	30	25	45	134.5	115.5	207.9
Lucifer	25	20	20	112.1	92.4	92.4
Scarlet	35	30	30	156.9	138.6	138.6
Jasmine	30	25	15	134.5	115.5	69.3
Nutmeg	25	25	20	112.1	115.5	92.4
Mean	32.5	25.6	29.4	145.7	118.4	135.7
SD	5.98	3.20	14.0	26.8	14.80	64.67
CORN/SORGHUM-BASED DIET	TEST 1 IAMS g/day	TEST 2 SORGHUM g/day	TEST 3 SORGHUM g/day	TEST 1 IAMS kcal/day	TEST 2 SORGHUM kcal/day	TEST 3 SORGHUM kcal/day
Abe	50	35	50	224.2	164.3	234.7
Lionall	50	35	50	224.2	164.3	140.8
Sophie	50	35	45	224.2	164.3	211.2
Tabatha	45	35	30	201.7	164.3	140.8
Rudolf	30	20	15	134.5	93.9	70.4
Eclaire	15	10	10	67.2	46.9	46.9
Meg	20	20	10	89.7	93.9	46.9
Romany	30	25	10	134.5	117.3	46.9
Mean	36.3	26.9	25.0	162.5	126.1	117.3
SD	14.33	9.61	16.24	64.24	45.12	76.0

Iams Original Formula Cat Food = 448.300 kcal/100g

Rice-Based Diet = 461.949 kcal/100g

Corn/Sorghum-Based Diet = 469.316 kcal/100g

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Average food intake (g/day) by male cats versus female cats is presented in Table 5 below. The rice-based diet is represented by Diet No. 5. The corn/sorghum-based diet is represented by Diet No. 6.

5 Table 5. Average Food Intake (g/day) Male v. Female

CAT NAME	GROUP NO.	CAT NO.	DIET NO.	MAINT. g/day	AD LIB. g/day	INCREASE g/day	% INCREASE
Leroy	2	1	5	69.13	116.78	47.65	68.93
Cooper	2	2	5	69.24	120.44	51.20	73.95
Lucifer	3	1	5	54.46	81.67	27.21	49.96
			Mean	64.28	106.30	42.02	64.28
Dash	2	3	5	62.10	100.44	38.34	61.74
Minstral	2	4	5	53.15	86.34	33.19	62.45
Scarlett	3	2	5	52.56	53.48	00.92	01.75
Jasmine	3	3	5	44.78	61.10	16.32	36.44
Nutmeg	3	4	5	45.33	54.66	09.33	20.58
			Mean	51.58	54.66	19.62	36.59
Abe	1	1	6	90.52	108.79	18.27	20.18
Lionall	1	2	6	70.73	69.74	-00.99	-1.40
Rudolf	4	1	6	44.88	84.19	39.31	87.59
			Mean	68.71	87.57	18.86	35.46
Sophie	1	3	6	77.92	97.24	19.32	24.79
Tabatha	1	4	6	77.81	88.48	10.67	13.71
Eclaire	4	2	6	51.79	70.24	18.45	35.62
Meg	4	3	6	42.00	45.16	03.16	07.52
Romany	4	4	6	35.58	53.69	18.11	50.90
			Mean	57.02	70.96	13.94	26.51

10 At the beginning and end of each feeding period, plasma glucose and insulin responses to a meal feeding of either the rice-based or corn/sorghum-based diet were measured for each cat. Serial venous blood samples were obtained for analysis of glucose and insulin concentration immediately before and for 24 hours after a 15-minute exposure to each experimental diet.

Results

The cats fed the corn/sorghum-based diet ate less and gained less weight than those cats fed the rice-based diet. Male cats fed the rice-based diet ate on average an additional 42.02 grams of food per day when fed ad libitum, as compared to when fed at maintenance. This corresponds to a 64.28% increase in food intake (g/day). While not quite as pronounced, female cats fed the rice-based diet ate on average an additional 19.62 grams of food per day when fed ad libitum, as compared to when fed at maintenance. This corresponds to a 36.59% increase in food intake (g/day).

Both male and female cats ate less on average when fed the corn/sorghum-based diet. Male cats fed the corn/sorghum-based diet ate on average an additional 18.86 grams of food per day when fed ad libitum, as compared to when fed at maintenance. This corresponds to a 35.46% increase in food intake (g/day). Again, while not quite as pronounced, female cats fed the corn/sorghum-based diet ate on average an additional 13.94 grams of food per day when fed ad libitum, as compared to when fed at maintenance. This corresponds to a 26.51% increase in food intake (g/day).

In addition, average plasma glucose and insulin concentrations were consistently lower in cats fed the corn/sorghum-based diet, compared to the results obtained from cats fed the rice-based diet. See Figs. 1-10 for a graphical representation of the results from this Example 1.

While certain representative embodiments and details have been shown for purposes of illustrating the invention, it will be apparent to those skilled in the art that various changes in the methods and apparatus disclosed herein may be made without departing from the scope of the invention, which is defined in the appended claims.

What is claimed is: